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10/825,893	04/16/2004	Zohar Yakhini	10020708-1	8979

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AGILENT TECHNOLOGIES, INC.
Legal Department, DL429
Intellectual Property Administration
P.O. Box 7599
Loveland, CO 80537-0599

EXAMINER	
NEGIN, RUSSELL SCOTT	
ART UNIT	**PAPER NUMBER**
1631	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/21/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	**Application No.** 10/825,893	**Applicant(s)** YAKHINI ET AL.
	Examiner Russell S. Negin	**Art Unit** 1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 December 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12 and 14-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-2,4,7,8,10-12,14-15,17,20-21,23 and 26-28* is/are rejected.

7)☒ Claim(s) *3,5,6,9,16,18,19,22,24 and 25* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Comments

It is acknowledged that claims 13 and 29 are cancelled.

Allowable Subject Matter

Claims 3, 5-6, 9, 16, 18-19, 22, and 24-25 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim Rejections - 35 USC § 101

The rejections of claims 1-12 and 14-28 under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter are withdrawn due to amendments made by applicants to the set of claims filed on 14 December 2006.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The rejections of claims 15-19 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention are withdrawn due to amendments made by applicant to the set of claims filed on 14 December 2006.

Claim Rejections - 35 USC § 103

The rejections of claims 1, 5, 6, 8, 9, 14, 18, and 19 under 35 U.S.C. 103(a) as being unpatentable over Larson et al. in view of Schadt et al. as applied to claims 1-4, 7-8, 10-11, and 14-17 in further view of Fredman [Discrete Mathematics, volume 11, 1975, pages 29-35] are withdrawn due to arguments made by applicant on page 12 of the Remarks of 14 December 2006.

The rejections of claims 20, 24 and 25 under 35 U.S.C. 103(a) as being unpatentable over Larson et al. in view of Schadt et al. in view of Chalmers as applied to claims 20-23 and 26-27 above, and further in view of Fredman are withdrawn due to arguments made by applicant on page 12 of the Remarks of 14 December 2006.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

<u>35 U.S.C. 103 Rejection #1</u>:

Claims 1-2, 4, 7-8, 10-12, 14-15, 17, and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Larson et al. [Calculus with Analytic Geometry, 1990, D. C. Heath and Company; Lexington, Massachusetts; Section 14.1, pages 785-795] in view of Schadt et al. [Journal of Cellular Biochemistry Supplement 37: 120-125, 2001].

1. A method for selecting a set of normalizing data points from n data sets, where n is at least 3, containing data points having values and identities, the method comprising: receiving n data sets; considering the data points to be distributed in an n-dimensional data-point space; determining one or more order-preserving sequences of data points within the n-dimensional data-point space; selecting, as normalizing data points, data points from the one or more order-preserving sequences; and storing the selected normalizing points in a computer memory as a basis for subsequent normalization of the n data sets.

2. The method of claim 1 wherein the one or more order-preserving sequences of data points is a single, longest order-preserving sequence of data points.

4. The method of claim 1 wherein the one or more order-preserving sequences of data points is a longest order-preserving sequence of data points having a shortest Euclidian distance accumulated along a path from an initial data point of the order-preserving sequence to a final data point of the order-preserving sequence.

7. The method of claim 1 wherein considering the data points to be distributed in an n-dimensional data-point space further includes, for each data point, considering the data point to have a value in each of n-dimensions, the value of a data-point in an ith dimension equal to the value of the data point in an ith data set, where 1 <= i <= n.

8. The method of claim 1 wherein determining an order-preserving sequence of data points within the n-dimensional data-point space further includes: for each currently considered dimension, ordering the data points with respect to the currently considered dimension; traversing the ordered data points in a first direction, determining a metric corresponding to a maximum subsequence for each data point in the first direction; and traversing the ordered data points in a second direction, determining a metric corresponding to a maximum subsequence for each data point in the second direction; summing the determined metrics for each data point in each dimension to produce a metric sum for each data point; and selecting as belonging to the maximum order-preserving sequence of data points those data points having a greatest metric sum.

10. The method of claim 8 wherein selecting, as normalizing data points, data points from the one or more order-preserving sequences further includes selecting data points of a single order-preserving sequence.

11. The method of claim 8 wherein selecting, as normalizing data points, data points from the one or more order-preserving sequences further includes selecting data points that most evenly partition the data points into subsets of data points.

12. Computer instructions stored in a computer readable medium that implement the method of claim 1.

14. A system for selecting a set of normalizing data points from n data sets, where n is at least 3, containing data points having values and identities, the system comprising: a processor; a memory; and computer instructions that select the set of normalizing data points from n data sets by receiving n data sets, considering the data points to be distributed in an n-dimensional data-point space, determining one or more order-preserving sequence of data points within the n-dimensional data-point space, and selecting, as normalizing data points, data points from the one or more order-preserving sequences; and storing the selected normalizing points in a computer memory as a basis for subsequent normalization of the n data sets.

15. The system of claim 14 wherein the one or more order-preserving sequences of data points is a single, longest order-preserving sequence of data points.

17. The system of claim 14 wherein the one or more order-preserving sequences of data points is a longest order-preserving sequence of data points having a shortest Euclidian distance accumulated along a path from an initial data point of the order-preserving sequence to a final data point of the order-preserving sequence.

28. Computer instructions stored in a computer readable medium that implement the method of claim 20.

The section of Larson et al., entitled, "Solid analytic geometry and vectors in space," describes the method used to normalize data in the instant application.

In this instance, there are three dimensions, and points are distributed in three-dimensional space (see the Figures 14.1 through 14.7 on pages 785-787 of Larson et al).

Terms of interest are defined in the instant specification, on page 17, lines 11-16:

> An order-preserving sequence us a sequence of data points in which the value of the data points within the sequence uniformly increase within the sequence. When a sequence is defined as an ordered subset of points with a data set, then a longest-order-preserving sequence ('LOPS') is the maximally sized, one or more ordered subsets of points selected from the data set that are ordered by signal strength or by some other associated value, parameter, or characteristic. A heaviest-order- preserving sequence ('HOPS') is the order preserving sequence with greatest sums of weights associated with data points in order-preserving sequence.

When applied to three-dimensions, the method of finding order-preserving sequences of data points in the instant application (i.e. Figure 11B) involves iteration(s) of determining traces of points in the same octant as the point before it with each subsequent point determining its own coordinate system. Figures 14.1, 14.4 and 14.6 on page 785, 786, and 787 of Larson et al. illustrate such an order-preserving sequence with a single set of three dimensional points forming a rectangular solid in the first octant and vectors pointing into the first octant. The rectangular solid illustrates eight discrete vertices → (0,0,0), (x,0,0), (0,y,0), (0,0,z), (x,y,0), (0,y,z), (x,0,z), and (x,y,z).

Consequently, two discrete data points in the first octant (0,0,0) and (x,y,z) illustrate an order preserving sequence as part of the rectangular solid illustrated in Figure 14.1 of Larson et al. The vertices connecting the edges of the rectangular solid housing these two vertices are interpreted to be the longest order preserving sequences of data points.

Figures 14.1, 14.4 and 14.6 of Larson et al. illustrate a line representing the shortest Euclidean path between the points.

Each data point has a value in each of the three dimensions.

The rectangular solid in Figure 14.1 of Larson et al. illustrates a situation where data points are ordered and traversed in the x, y, and z dimensions (each edge of the rectangular solid illustrates such a traversal in each dimension) in order to find greatest metric sums based on changes in each of the three dimensions. Additionally, there are several iterative paths one can take from (0, 0, 0) to (x, y, z) via varying the order in which the dimensions are traversed.

Larson et al. does not possess the computer or automated limitations of the instantly rejected claims.

Schadt et al., however, in the article entitled, “Feature extraction and normalization algorithms for high density oligonucleotide gene expression array data,” states in its abstract:

> Algorithms for performing feature extraction and normalization on high-density oligonucleotide gene expression arrays, have not been fully explored, and the impact these algorithms have on the downstream analysis is not well understood. Advances in such low-level analysis methods are essential to increase the sensitivity and specificity of detecting whether genes are present and/or differentially expressed. We have developed and implemented a number of algorithms for the analysis of expression array data in a software application, the DNA-Chip Analyzer (dChip). In this report, we describe the algorithms for feature extraction and normalization, and present validation data and comparison results with some of the algorithms currently in use.

In terms of the computerized aspects of the limitations, Figure 3 on page 124 of Schadt et al. illustrates the output of the computer software employed in the analysis. The last sentence of the article of Schadt et al. emphasizes the use of computing in finding order preserving sequences by stating on page 125:

> We have implemented the algorithms described in this article in our software application, the DNA-Chip Analyzer (dChip). In addition to the implementations of the algorithms described here, dChip also performs image gradient and artifacts correction, array and probe outlier detection... dChip has a user interface that allows arrays and experiments to be logically grouped, and provides higher level group comparison functions and hierarchical clustering (Fig. 3). The software is available at www.dchip.org.

It would have been obvious at the time of the instant invention for someone of ordinary skill in the art to modify the three dimensional analysis of Larson et al. by use automated model of Schadt et al. because Schadt et al. has the advantage of applying the analogous order preserving sequence algorithm executed in Larson et al. with the advantage of using computerized methods for extended mathematical analysis as described in the passage above (i.e. image gradient and artifacts correction, array and

probe outlier detection, higher level group comparison functions, and hierarchical clustering) for more efficient and complex analyses of data.

35 U.S.C. 103 Rejection #2:

Claims 20-21, 23 and 26-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Larson et al. in view of Schadt et al. as applied to claims 1-2, 4, 7-8, 10-12, 14-15, 17, and 28 above in view of Chalmers: [http://web.archive.org/web/20021008184825/http://www.s2.chalmers.se/~agrell/hypercubes (Accessed on August 28, 2006; website last updated in 2002)].

Claims 20-21, 23 and 26-27 state:

20. A method for selecting a set of normalizing data points from n data sets, where n is at least 4 and even, containing data points having values and identities, the method comprising: receiving n data sets; considering the data points to be distributed in n/2 2-dimensional data-point spaces; determining one or more order-preserving sequences of data points for each of the n/2 2-dimensional data-point spaces; selecting, as normalizing data points, data points from the order-preserving sequences; and sorting the selected normalizing points in a computer memory as a basis for subsequent normalization of the n data sets.

21. The method of claim 20 wherein the one or more order-preserving sequences of data points is a single, longest order-preserving sequence of data points.

23. The method of claim 20 wherein the one or more order-preserving sequences of data points is a longest order-preserving sequence of data points having a shortest Euclidian distance accumulated along a path from an initial data point of the order-preserving sequence to a final data point of the order-preserving sequence.

26. The method of claim 20 wherein determining an order-preserving sequence of data points within a 2-dimensional data-point space further includes: for each currently considered dimension, ordering the data points with respect to the currently considered dimension; traversing the ordered data points in a first direction, determining a metric corresponding to a maximum subsequence for each data point in the first direction; and traversing the ordered data points in a second direction, determining a metric corresponding to a maximum subsequence for each data point in the second direction;

summing the determined metrics for each data point in each dimension to produce a metric sum for each data point; and selecting as belonging to the maximum order-preserving sequence of data points those data points having a greatest metric sum.

27. The method of claim 20 wherein selecting, as normalizing data points, data points from the one or more order-preserving sequences further includes selecting data points which occur in the one or order-preserving sequences computed for greater than a threshold fraction of the n/2 2-dimensional data-point spaces.

Larson et al. in view of Schadt et al. as applied to claims 1-2, 4, 7-8, 10-12, 14-15, 17, and 28 fails to teach normalization of hybridization data greater than three dimensions.

On page 1 of Chalmers, entitled, "A glimpse into high-dimensional space," multidimensional hypercubes are illustrated on two dimensional paper.

It would have been obvious to someone of ordinary skill in the art at the time of the instant invention to modify Larson et al. in view of Schadt et al. as applied to claims 1-2, 4, 7-8, 10-12, 14-15, 17, and 28 above in further view of Chalmers et al. to result in the instantly claimed invention because while Larson et al. in view of Schadt et al. illustrates the appropriate algorithm for three dimensions, Chalmers has the capability and advantage of being able to employ the same algorithm for higher dimensions for the purpose of adding degrees of freedom and additional dimensions.

Response to Arguments

Applicant's arguments filed 14 December 2006 have been fully considered but they are not persuasive.

The arguments of the applicant concerning the prior art rejections are on pages 10-13 of the Remarks of 14 December 2006.

First, applicants argue on page 10 of the Remarks of 14 December 2006:

> Larsen [sic] is unrelated to the subject matter to which the current claims are directed. The portion of Larsen [sic] by the Examiner is an introductory text on Cartesian space, vectors, and direction cosines. This material falls into the general topic of continuous mathematics, while, by contract, the current application is related to discrete mathematics.

In response, while the textbook of Larson et al. is on the subject of calculus, the cited Figures of the textbook of Larson et al. are on discrete mathematics in three-dimensional space. The fact that the textbook is on the subject of calculus does not limit the text of the book to be purely on continuous mathematics.

Applicant continues on page 10 of the Remarks of 14 December 2006 with a discussion of discrete vs. continuous mathematics:

> This [application] is [in] an area of discrete mathematics referred to as fully ordered sets and partially ordered sets. Lattices and set theory are other topics in discrete mathematic related to order-preserving sets. In order to select as order-preserving sequence of points, an ordering function must be defined, as well as the set of points from which an order preserving sequence is to be selected. Larsen [sic] discusses or suggests nothing of the sort. A continuous function, such as a plane or line in Cartesian space, contains an infinite set of points and, depending on how the ordering function is defined, would generally contain an infinite number of order-preserving points or most geometrically based ordering functions. Infinite sets are not useful for data normalization, because they are, obviously, computationally intractable.

With regard to Larson et al. showing order preserving sequences in Figure 14.1, 14.4, and 14.6, applicants state:

> They do not, and these figures are not related to the current disclosure. Instead, they show an octant of Cartesian space, application of the Pythagorean Theorem, and the notation for a vector in Cartesian space, as clearly stated by Larson. Larsen [sic] does not teach, mention, or suggest anything at all concerning order-preserving sequences.

In response to these two passage in the Remarks of the applicant, Figures 14.1, 14.4 and 14.6 on pages 785-787 of Larson et al. illustrate the definition of applicant of a discrete order preserving sequence. As is stated in the specification of page 18, lines 11-12:

> An order-preserving sequence uses a sequence of data points in which the value of the data points within the sequence uniformly increase within the sequence.

Figure 14.1 on page 785 of Larson et al. fits the description of this definition. This drawing comprises eight discrete points (or vertices) of a rectangular solid. The point (x, y, z) is greater than the origin (0, 0, 0) uniformly in each of the three dimensions; consequently these two points form an order preserving sequence in the first octant of a three-dimensional grid. Figure 14.4 on page 786 of Larson et al. illustrates the same principle between points P (x1, y1, z1) and Q (x2, y2, z2), where (x2 > x1; y2 > y1, and z2 > z1). P and Q form an order preserving sequence. Figures 14.6 and 14.7 on page 787 of Larson et al. five the same illustrations as Figure 14.1 and 14.4, respectively, but in vector form.

Applicant continues to argue on pages 11 and 12 of the Remarks of 14 December 2006 that the Figures of Larson et al. are representations in continuous mathematics. However, as the drawings of Larson et al have vertices and data points, they are interpreted as discrete and fitting the definition of order preserving sequence, and longest order preserving sequence.

On page 11 of the Remarks of 14 December 2006, applicant claims not to understand the statements from the previous Office action of 8 September 2006:

> ..rectangular solid in Figure 14.1 of Larson et al. illustrates a situation where data points are ordered and traversed in all three directions in order to find greatest metric sums based on changes in each of the three dimensions.

> ...method of finding order-preserving sequences of data points in the instant applications involves interaction(s) of determining traces of points in the same octant as the point before it with each subsequence point determining its own coordinate system.

In response, the first statement refers to Figure 14.1 of Larson et al., which illustrates a rectangular solid with eight vertices → (0,0,0), (x,0,0), (0,y,0), (0,0,z), (x,y,0), (0,y,z), (x,0,z), and (x,y,z). The edges of the solid form a path from the origin to (x, y, z) to find the greatest changes in each of the three dimensions to arrive at the endpoint (x, y, z) from the staring point (0, 0, 0); each of the three dimensions (not "directions" as stated by the applicant) is traversed to arrive at the end point from the starting point. Additionally, the point (x, y, z) is geometrically the vector sum of any three edges (i.e. vectors) connecting the origin to this point. There are several iterations involving sets of three vectors that can be employed to arrive at the endpoint in Figure 1 of (x, y, z).

Applicant brings up Figure 11B of the instant applicant, which is the Figure described by Figure 14.1 of Larson et al. Applicant, however, indicated that Figure 11B is merely an abstract illustration, and that dimensions are meant to be used as data sets as shown in Figure 13 of the instant application. Yet, there is no language in the specification or disclosure limiting dimensions to not include dimensions of Cartesian space. The instant claims are broad enough to encompass the Cartesian dimensions illustrated in both Figure 11 of the current application and Figures 14.1, 14.4, 14.6, and 14.7 of Larson et al.

Applicant next argues on page 12 of the Remarks of 14 December 2006, that the instant disclosure does involve the 'greatest sum of weights'. In response, the text of the initial rejection has been modified.

Applicant next argues with respect to Chalmers on page 12 of the Remarks of 14 December 2006:

> While 2-dimensional renderings of hyper-dimensional mathematical objects are fascinating and beautiful, they have nothing to do with order-preserving sequences and selection of normalizing data points.

In response, if Chalmers taught every limitation of the set of claims, it would be an anticipatory prior art rejection. It is currently used as part of an obviousness prior art rejection where, when used in a combination with Larson et al. and Schadt et al., describes all of the features of the currently claimed invention. In particular, Chalmers shows the applicability of Larson et al. and Schadt et al. to higher dimensionalities where there are additional degrees of freedom to govern the sequence selection.

Applicant has arguments pertaining to the Schadt et al. reference on pages 12-13 of the Remarks of 14 December 2006 where is it stated:

> Schadt uses a simple linear interpolation and difference threshold technique, expressed in the equations on page 123, to try to approximate an invariant set. The difference metric involves an absolute value, indicating that it is a scalar value, such as a distance, rather than a directional value, and therefore cannot be used to select an order-preserving sequence with respect to rank, since ranks below and above a selected rank reference point would have an identical difference metric computed by Schadt.

In response, the study of Schadt et al. is employed to show an analogous method of the instant application with the purpose of showing the ease and efficiency of automating the statistical process. While Schadt et al. does not show all of the limitations of the claimed instant application, when used in combination with Larson et al. and/or Chalmers, the limitations of the instantly claimed invention are met.

Conclusion

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the central PTO Fax Center. The faxing of such pages must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The Central PTO Fax Center Number is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Russell Negin, Ph.D., whose telephone number is (571) 272-1083. The examiner can normally be reached on Monday-Friday from 7am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisor, Irem Yucel, Supervisory Patent Examiner, can be reached at (571) 272-0781.

Information regarding the status of the application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information on the PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RSN
14 March 2007

14 March 2007

16 March 2007
JOHN S. BRUSCA, PH.D
PRIMARY EXAMINER